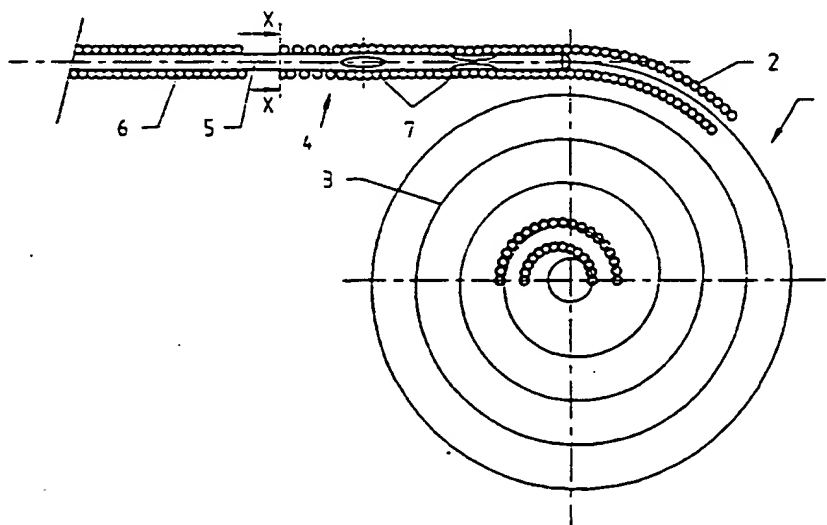


## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

|   |  |   |
|---|--|---|
| (51) International Patent Classification <sup>6</sup> :<br><b>A61B 17/12</b>  | <b>A1</b>  | (11) International Publication Number: <b>WO 97/42881</b><br>(43) International Publication Date: 20 November 1997 (20.11.97) |
| <p>(21) International Application Number: PCT/EP97/02300</p> <p>(22) International Filing Date: 6 May 1997 (06.05.97)</p> <p>(30) Priority Data:<br/> 196 21 157.3      14 May 1996 (14.05.96)      DE<br/> 197 04 269.4      5 February 1997 (05.02.97)      DE</p> <p>(71) Applicant (for all designated States except US): PFM PRODUKTE FÜR DIE MEDIZIN GMBH [DE/DE]; Wankelstrasse 60, D-50996 Köln (DE).</p> <p>(72) Inventors; and<br/> (75) Inventors/Applicants (for US only): BOOSFELD, Christoph [DE/DE]; Wilhelmstrasse 89, D-52070 Aachen (DE). FREUDENTHAL, Franz [DE/DE]; Verdistrasse 1, D-53115 Bonn (DE).</p> <p>(74) Agents: FLEISCHER, Holm et al.; Sternagel &amp; Fleischer, Braunsberger Feld 29, D-51429 Bergisch Gladbach (DE).</p> | <p>(81) Designated States: JP, US, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p><b>Published</b><br/> <i>With international search report.</i></p> |   |

(54) Title: STRENGTHENED IMPLANT FOR BODILY DUCTS



## (57) Abstract

An implant (1) for closing passages in organs is proposed, comprising a primary coil (2) consisting of a resilient material, where the implant (1), in an operational state, forms a secondary coil (3) of greater diameter than that of the primary coil (2), where the implant (1) can be converted by a guide element (5) from the shape of the secondary coil (3) into a transporting state in which the implant (1) adopts an elongate shape, and the implant (1) once again assumes the operational state by removal of the guide element (5). In order to improve the success of treatment, it is proposed, for achieving a better securing of the implant (1) in a larger passage of an organ, that the primary coil (2) has areas of different transverse spring rate along its longitudinal extent. A set is furthermore proposed with an implant (1) according to the invention, and a device for applying such an implant (1) with a guide element (5).

## PATENT CLAIMS

1.        Implant (1) for closing passages in organs,  
5   comprising a primary coil (2) of a resilient material, where  
the implant (1), in an operational state, forms a secondary  
structure (3) of greater diameter than that of the primary  
coil (2), where the implant (1) can be converted by a guide  
element (5, 23, 24) from the shape of the secondary structure  
10 (3) into a transporting state in which the implant (1) adopts  
an elongate shape, and the implant (1) once again assumes the  
operational state by means of removal of the guide element  
(5, 23, 24), characterized in that the primary coil (2) has  
areas of different transverse spring rate along its  
15 longitudinal extent.
2.        Implant (1) according to Claim 1, characterized in  
that the secondary structure (3) has areas (11) with greater  
radii of curvature and areas (12) with smaller radii of  
curvature, and the primary coil (2), in the areas (11) of  
20 large radii of curvature of the secondary structure (3),  
possesses a greater transverse spring rate than in the areas  
(12) of smaller radii of curvature of the secondary structure  
(3).
3.        Implant (1) according to either of Claims 1 and 2,  
25 characterized in that the primary coil (2) has at least one  
additional body (9, 13) by means of which the different  
transverse spring rate is achieved.
4.        Implant (1) according to one of the preceding claims,  
characterized in that the primary coil (2) includes, on at  
30 least one part of its length, at least one further primary  
coil (9).
5.        Implant (1) according to Claim 4, characterized in

that at least one end section (4, 8) of the primary coil (2) includes, on at least one part of its length, at least one further primary coil (9).

6. Implant (1) according to either of Claims 4 and 5, characterized in that both end sections (4, 8) of the primary coil (2) each include, on at least one part of their lengths, at least one further primary coil (9).

7. Implant (1) according to one of Claims 4 - 6, characterized in that at least one end section (4, 8) of the primary coil (2) includes, on at least one part of the length of the further primary coil (9), at least one additional primary coil.

8. Implant (1) according to one of Claims 4 - 7, characterized in that both end sections (4, 8) of the primary coil (2) each include, on at least one part of the lengths of the further primary coils (9), at least one additional primary coil.

9. Implant (1) according to one of Claims 4 - 8, characterized in that the turns of the primary coil (2) or of the primary coils (2, 9) are stretched out in the area of a proximal end section (4).

10. Implant (1) according to one of Claims 4 - 9, characterized in that the primary coil (2) or the primary coils (2, 9) have a noncircular, tapered or reduced cross-section in the area of the proximal end section (4).

11. Implant (1) according to Claim 10, characterized in that the primary coil (2) or the primary coils (2, 9) have an approximately polygonal cross-section in the area of the proximal end section (4).

12. Implant (1) according to Claim 10, characterized in that the primary coil (2) or the primary coils (2, 9) have an approximately triangular cross-section in the area of the

proximal end section (4).

13. Implant (1) according to one of Claims 4 - 12, characterized in that the further primary coils (9) and the additional primary coils have approximately the same external dimensions as the primary coil (2).

14. Implant (1) according to one of Claims 4 - 13, characterized in that the further primary coils (9) and the additional primary coils are wound between the turns of the primary coil (2).

10 15. Implant (1) according to one of Claims 1 - 3, characterized in that the primary coil (2) has, within its lumen, a core (13) having areas (16, 17) of different bending rigidity, at least relative to a reference plane (21), along its longitudinal extent.

15 16. Implant (1) according to Claim 15, characterized in that the core (13) contains a plurality of wires (14, 15), the number of wires in areas (16) of greater bending rigidity being greater than in areas (17) of lower bending rigidity.

17. Implant (1) according to Claim 15, characterized in  
20 that the core (13) contains one individual wire (19) or a number of wires remaining the same over the entire length of the primary coil (2), where the wire (19) or the wires has/have a changing diameter, with a greater diameter in areas (16) of greater bending rigidity, and a smaller  
25 diameter in areas (17) of lower bending rigidity.

18. Implant (1) according to Claim 15, characterized in that the core contains one individual wire or a number of wires remaining the same over the entire length of the primary coil, where the wire or the wires has/have a circular  
30 cross-sectional surface area in areas of lower bending rigidity, and a polygonal cross-sectional surface area in areas of greater bending rigidity.

19. Implant (1) according to Claim 15, characterized in that the polygonal cross-sectional surface area is triangular or rectangular, preferably square.

20. Implant (1) according to Claim 15, characterized in  
5 that the core (13) contains one or more flat wires (20).

21. Implant (1) according to Claim 20, characterized in that the flat wire (20) or the flat wires is/are arranged inside the primary coil (2) in such a way that, upon formation of the secondary structure (3) of the implant (1),  
10 the flat wire (20) or the flat wires, in areas (12) of the secondary structure (3) having small radii of curvature, is/are bent out from the plane (21) which extends parallel to the broad side of the flat wire (20), and, in areas (11) of the secondary structure (3) having by comparison greater  
15 radii of curvature, is/are bent within this plane (21).

22. Implant (1) according to Claim 15, characterized in that the core (13) contains a braid (22) which has areas with a different number of windings of the individual wires per unit of length of the braid (22).

20 23. Implant (1) according to one of Claims 15 - 22, characterized in that the primary coil (2) and/or the core (13) consist of a memory metal.

24. Implant (1) according to one of Claims 15 - 23, characterized in that the implant (1) has, at the proximal  
25 end (4), a positioning device (18) which is arranged either on the primary coil (2) or on the core (13) and is advantageously designed as an eyelet.

25. Implant (1) according to one of the preceding claims, characterized in that, by twisting the primary coil (2), the  
30 secondary structure (3) assumes the shape of a cylinder, a cone, a double cone with greater radii at the ends, a double cone with different radii at the ends, a cylinder in which

turns of the secondary structure (3) with different radii alternate with each other, two spirals connected by a cylindrical section, a double rosette, a double cone, where the turns of the second cone are wound onto the turns of the first cone, or assumes the shape of a plurality of horizontal eight shapes.

26. Set containing an implant (1) according to one of the preceding claims, and an insertion device for the implant (1) with an insertion catheter (23) and a guide element (5, 24), which can be connected releasably to the implant (1) and is movable inside the insertion catheter (23).

27. Set according to Claim 26, with an implant according to one of Claims 1 - 14, characterized in that, in the area of its distal end, the guide element (5) has a widened portion (7) on one part of its length, in an axis transverse to the longitudinal axis of the guide element (5).

28. Set according to Claim 27, characterized in that, in the area of its distal end, the guide element (5) has at least one further widened portion (7) on one part of its length, in an axis transverse to the longitudinal axis of the guide element (5) and approximately transverse to the widened portion (7).

29. Set according to either of Claims 27 and 28, characterized in that the widened portion (7) amounts to about 1.15 times the diameter of the guide element (5) outside the areas of the widened portions (7).

30. Set according to Claim 26, with an implant according to Claim 24, characterized in that the guide element is a positioning wire, which has a hook which engages in the positioning device of the implant.

31. Set according to Claim 26, with an implant according to Claim 24, characterized in that the guide element is a

**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

**BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☒ **BLACK BORDERS**
- ☒ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☒ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☒ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**